

REMARKS

OATH/DECLARATION

Applicant hereby submits a substitute Declaration, in which the residence address of the inventor Stephen Christgau has been provided.

SEQUENCE COMPLIANCE

In this Amendment, Applicant has amended the specification and Claims 1, 10 and 13 to proper refer the sequence of "Sequence Listing" as "SEQ ID NO: 1". In addition, Applicant hereby states that the submission, filed in accordance with 37 CFR 1.821(g), herein does not include new matter.

RESTRICTION REQUIREMENT

The Examiner has required the Applicant to elect a specific amino acid sequence. Since the Applicant previously elected the invention of Group I, Claims 1 – 9, drawn to methods of assay of collagen type II or fragments thereof, for further examination, with traverse.

It is respectfully submits that the inventions of Groups I and II are related to a single general inventive concept under PCT Rule 13.1 because they define a contribution over the prior art. The present invention is a single general inventive concept which is a method of assay of a collagen type II peptide released during collagen processing thereof in a biological sample. Indeed, the present invention also covers a binding partner which is reactive with an epitope comprised in the amino sequence HRGYPGLDG, in the context of unwound collagen type II or fragment thereof but not in the context of the wound form of collagen type II.

In contrast, the Holmdahl reference covers a composition containing three polypeptides, wherein each contains a triple helix formation sequence. Therefore, the binding partner described in the present invention can not recognize the epitope HRGYPGLDG in triple helical structure described by Holmdahl. Therefore, the present invention is clearly different from Holmdahl reference.

The Examiner indicated that Holmdahl teaches the peptide GHRGYPGL (SED ID NO 22) which consists of amino acid 1-7 of the 9 amino acid HRGYPGLDG peptide. The peptide of Holmdahl shares 7 contiguous amino acids in common with the SED ID No 1 peptide. Applicant respectfully submits that the binding partner in the present invention does not recognize the epitope in the wound form of type II collagen. Coll2-1 is released during triple helix degradation by collagenases and gelatinases, whereas Coll2-2 is not generated as a result of collagenase activity. Further, the detection of these two peptides probably increase discriminative power of the present assay.

The Examiner also indicated that Holmdahl teach an immunological binding partner (antibody in human serum samples) that is capable of specifically binding to the SED ID NO 22 peptide. Applicant respectfully submits that the binding partner teaches by Holmdahl is capable of specifically bind the triple polypeptide complex, and not the linear sequence SED ID NO 22. The immunogenicity of the complex seems to be rather linked to the complex association of three polypeptides than to the presence of the sequence SED ID 22 in this complex.

Regarding the Examiner's suggestion that the immunological partner defined by Holmdahl could also bind the SEQ ID NO 1. Applicant respectfully submits that this is not correct. Applicant has clearly demonstrated that be immunogen, the peptide of the present invention needs to be released from the wound type II collagen molecule.

Applicant has never found endogenous immunological binding partners that bind the linear form of the peptide SEQ NO 1 in the serum of patient with OA or RA.


Because the inventions of Groups I and II are related to a single general inventive concept under PCT Rule 13.1 for the reasons stated above, withdrawal of the election of species requirement is respectfully requested.

An action on the merits of all of the claims and a Notice of Allowance thereof are also respectfully requested.

Respectfully submitted,

JACOBSON HOLMAN PLLC

Date: May 4, 2007
(202) 638-6666
400 Seventh Street, N.W.
Washington, D.C. 20004

By 
John C. Holman
Registration No. 22,769

Enclosed:

Substitute Declaration